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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,168	07/25/2005	Jens Lillegaard	P70187US0	6969
136	7590	12/20/2007	EXAMINER	
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			HAND, MELANIE JO	
			ART UNIT	PAPER NUMBER
			3761	
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			12/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,168	LILLEGAARD, JENS	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/1/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 1, 2007 has been entered.

Response to Arguments

2. Applicant's arguments, see Remarks, filed October 1, 2007, with respect to the rejection(s) of claim(s) 1-20 under 35 U.S.C. 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on October 1, 2007 was filed after the mailing date of the final action on April 2, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 14 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ciok et al (WO 01/21115 A1).

With respect to **claim 14**: Ciok teaches a collecting bag for human body wastes, comprising: a bag member 1 including at least two outer film blanks 2,3 with joined edges accomplished by a seam 4 defining the outer contours of the bag member, said outer contours defining a fluid-retaining area of said bag member 1. An inlet opening (not shown) is provided in film blank 3. A discharge portion 6 is present at a distance from the inlet opening in a lower portion of the bag member 1, and includes a closure device 7 for bringing the bag from a discharge position, in which the bag is open, to a position of use, in which the bag is closed. As can be seen in Fig. 1, the discharge portion 6 defines a longitudinal direction in that it lies parallel to the longer, major axis of the bag. An accommodating element 8 is present within the outer contours of the bag member for accommodating at least a part of the discharge portion 6 in the position of use of the bag. Bag member 1 includes at least a first substantially tubular inner film element and a second substantially tubular inner film element as can be seen in a cross-section of bag 1 in Fig. 4, each substantially tubular inner film element being within said fluid-retaining area of said bag member 1 and attached to the inner side of each outer film blank by a respective pair of joint sections, as can also be seen in Fig. 4. The first and second substantially tubular inner film elements are respectively situated on the respective side of a dividing line through the center of basis portion 9 that is substantially parallel with the longitudinal direction defined by the discharge portion 6. Each substantially tubular inner element is provided in the lower portion of the bag member 1 adjacent discharge portion 6. The accommodating element 8 includes an element providing at least one opening for receiving at least a part of the discharge portion 6 in the position of use of the bag, said opening extending substantially transversely between

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respective pairs of joint sections of the first and the second substantially tubular inner film elements, respectively. (Fig. 4, Page 4, line 21 – Page 6, line 15, Page 6, lines 20 – 25)

With respect to **claim 20**: The bag member 1 of Ciok is substantially symmetrical with respect to said dividing line, as can be seen in the cross sectional view of bag member 1 in Fig. 4.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-7, 10-13, 15-17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ciok (WO 01/21115 A1).

With respect to **claim 1**: Ciok teaches a collecting bag for human body wastes, comprising: a bag member 1 including at least two outer film blanks 2,3 with joined edges accomplished by a

seam 4 defining the outer contours of the bag member, said outer contours defining a fluid-retaining area of said bag member 1. An inlet opening (not shown) is provided in film blank 3. A discharge portion 6 is present at a distance from the inlet opening in a lower portion of the bag member 1, and includes a closure device 7 for bringing the bag from a discharge position, in which the bag is open, to a position of use, in which the bag is closed. As can be seen in Fig. 1, the discharge portion 6 defines a longitudinal direction in that it lies parallel to the longer, major axis of the bag. An accommodating element 8 is present within the outer contours of the bag member for accommodating at least a part of the discharge portion 6 in the position of use of the bag. Bag member 1 includes at least a first substantially tubular inner film element and a second substantially tubular inner film element as can be seen in a cross-section of bag 1 in Fig. 4, each substantially tubular inner film element being within said fluid-retaining area of said bag member 1 and attached to the inner side of each outer film blank by means of at least one joint as can also be seen in Fig. 4. The first and second substantially tubular inner film elements are respectively situated on each side of a dividing line through the center of basis portion 9 that is substantially parallel with the longitudinal direction defined by the discharge portion 6. Each of said substantially tubular inner film elements have, when the bag is substantially empty, a distal fold adjacent seam 4 and a proximal fold adjacent basis portion 9 with respect to said dividing line extending through the center of basis portion 9. A first joint is present between the first substantially tubular inner film element and one outer film blank 2 and a second joint is present between the second substantially tubular inner film element and said one outer film blank 2, each joint respectively including at least one proximal joint section at or near the proximal fold and at least one distal joint section at or near the distal fold.

The first and second joints are angled toward the discharge portion at their upper ends, therefore, for each of said first and second joints, a first distance between at least a lower part of

the proximal joint section (the lower end of the joint closest to the discharge portion 6) and the proximal fold is smaller than a second distance between at least a lower part of the distal joint section and the distal fold. The accommodating element 8 provides at least one opening for receiving at least a part of the discharge portion 6 in the position of use of the bag, said opening extending substantially transversely between the proximal joint sections of the first and the second substantially tubular inner film elements, respectively. (Fig. 4) The proximal joint sections define a recessed space in the form of an open receptacle having basis portion 9 therebetween that overlies the longitudinal dividing line, said recessed space being in the lower portion of the bag adjacent said discharge portion 6 and fully accommodating said closure device 7 in the in-use position so that said closure device 7 when received within said opening does not protrude outside an arched plane defined by an overall shape of said bag member.

(Fig. 4, Page 4, line 21 – Page 6, line 15, Page 6, lines 20 – 25)

Ciok does not teach that the joint sections are angled toward the discharge portion at their lower end, however a receptacle defined by joint sections that are angled as claimed would be equally capable of accommodating the discharge portion. Thus it would be obvious to one of ordinary skill in the art to modify the article of Ciok such that the joint sections are angled toward the discharge portion at their lower end to define a space sized to accommodate said discharge portion.

With respect to **claim 2**: The proximal joint sections taught by Ciok between the first and second substantially tubular inner film elements 2,3, respectively, (collectively defining periphery 9a of basis portion 9) and one outer blank 2, extend obliquely with respect to said dividing line such that said proximal joint sections converge in the direction of the discharge portion 6 to define said recessed space. (Fig. 2)

With respect to **claim 3**: The second distance between the distal joint section and the distal fold is necessarily larger than the first distance between the lower part of the proximal joint section and the proximal fold, as the joint sections are angled inward toward the discharge portion 6 adjacent said proximal fold. The second distance is also necessarily smaller than a third distance between the upper part of the proximal joint section and the proximal fold due to said angling of the joint sections.

With respect to **claim 4**: Ciok does not explicitly teach an angle of inclination as claimed. However, it would be obvious to one of ordinary skill in the art to modify the angle so as to meet the claimed range, as both the accommodating means 8 of Ciok and the claimed accommodating means are bounded by the respective proximal folds toward which the oblique joint sections converge, and Ciok teaches that the accommodating means 8 is sized to accommodate the discharge portion and closure device 7, as is the claimed accommodating means. Thus the size of the accommodating means is a design need. The angle of inclination would be based upon the dimensions of the proximal folds and the accommodating means. If there is a design need or a market pressure to solve a problem, and there are a finite number of identified, predictable solutions (i.e. dimensions for the proximal folds that will define an accommodating means size to fit the discharge portion), a person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation.

With respect to **claim 5**: A distance between the lower ends of the oblique joint sections substantially corresponds to the cross-sectional dimensions of the corresponding part of the

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discharge portion 6, as the lower ends are the ends closest the proximal folds which define the boundaries of the accommodating means 8 which is specifically sized to accommodate the discharge portion 6 and closure device 7. (Page 5, lines 11-25)

With respect to **claim 6**: Each proximal joint section is considered herein to be substantially parallel with its respective proximal fold, inasmuch as it is coincident with said fold in the portion of the proximal section that extends vertically up and downward as is seen in Fig. 2, such that the first distance between the proximal joint section and the proximal fold is substantially uniform along a length of said proximal joint section. The said first distance is smaller than the second distance between the distal joint section and the distal fold, owing to the angling of each joint away from the proximal fold as one progresses along the joint in the general direction of the distal fold.

With respect to **claim 7**: A distance between the proximal joint sections (i.e. the lower ends of the oblique joint sections) substantially corresponds to the cross-sectional dimensions of the corresponding part of the discharge portion 6, as the lower ends are the ends closest the proximal folds which define the boundaries of the accommodating means 8 which is specifically sized to accommodate the discharge portion 6. (Page 5, lines 11-25)

With respect to **claim 10**: Each of said joint sections is reinforced by welding along the periphery 9a, which is considered herein to be spot welding inasmuch as only discrete portions are welded rather than a simultaneous welding of the entire film blanks 2,3 to one another. Spot welding is a reinforcing portion that is disclosed by applicant, thus the prior art of Ciok meets the limitation of claim 10.

With respect to **claim 11**: Ciok does not teach additional substantially tubular inner film elements provided in the bag member. However the tubular elements are a result of joint patterns, therefore it would be obvious to one of ordinary skill in the art to modify the article of Ciok by modifying the joint pattern so as to have additional tubular elements provided in bag member 1 with a reasonable expectation of success. It has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis Paper Co. v. Bémis. Co.* 193 USPQ 8 (7th Cir. 1977)

With respect to **claim 12**: Both substantially tubular inner elements are provided in the area of the bag member situated adjacent the discharge portion 6. (Fig. 4)

With respect to **claim 13**: The bag member 1 of Ciok is substantially symmetrical with respect to said dividing line, as can be seen in the cross sectional view of bag member 1 in Fig. 4.

With respect to **claim 15**: The joint sections of each pair of joints that are proximal to said dividing line extend obliquely with respect to said dividing line such that said lower ends of said proximal joint sections converge in the direction of the discharge portion 6 to define said recessed space. The oblique joint sections inherently and necessarily shape the bag when it is at least partly filled so that a bag thickness measured between the two outer film blanks from front to back is smaller at said lower ends where said proximal joint sections converge than at upper ends of said proximal joint sections, owing to the decreasing area size defined by the joint sections between the sections and the dividing line. The decreased-size area is capable of

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holding less fluid, thus the thickness will be less than at the upper ends of said proximal joint sections, where there is a larger area available for fluid to fill when the bag is at least partially filled.

Ciok does not teach that the joint sections are angled toward the discharge portion at their lower end, however a receptacle defined by joint sections that are angled as claimed would be equally capable of accommodating the discharge portion. Thus it would be obvious to one of ordinary skill in the art to modify the article of Ciok such that the joint sections are angled toward the discharge portion at their lower end to define a space sized to accommodate said discharge portion.

With respect to **claim 16**: Ciok does not explicitly teach an angle of inclination as claimed.

However, it would be obvious to one of ordinary skill in the art to modify the angle so as to meet the claimed range, as both the accommodating means 8 of Ciok and the claimed accommodating means are bounded by the respective proximal folds toward which the oblique joint sections converge, and Ciok teaches that the accommodating means 8 is sized to accommodate the discharge portion and closure device 7 (Page 5, lines 11-25), as is the claimed accommodating means. Thus the size of the accommodating means is a design need. The angle of inclination would be based upon the dimensions of the proximal folds and the accommodating means. If there is a design need or a market pressure to solve a problem, and there are a finite number of identified, predictable solutions (i.e. dimensions for the proximal folds that will define an accommodating means size to fit the discharge portion), a person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation.

With respect to **claim 17**: A distance between the proximal joint sections (i.e. the lower ends of the oblique joint sections) taught by Ciok substantially corresponds to the cross-sectional dimensions of the corresponding part of the discharge portion 6, as the lower ends are the ends closest the proximal folds which define the boundaries of the accommodating means 8 which is specifically sized to accommodate the discharge portion 6.

With respect to **claim 21**: The said smaller bag thickness at said proximal joint section lower ends inherently and necessarily provides a recessed space in the form of an open receptacle having basis portion 9 between the oblique joint sections adjacent the discharge portion 6 in which said closure device 7 is fully accommodated in the in-use position so that said closure device 7 when received in said opening does not protrude outside an arched plane defined by the overall shape of the bag member, as can be seen in Fig. 6. (Page 5, lines 21-28)

9. Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ciok ('115) in view of Austin (U.S. Patent No. 4,790,834).

With respect to **claim 8**: Ciok does not teach that the accommodating element is a comfort layer overlying said one outer film blank 2. However, such a layer attached to the outer film blank is simply another means for housing the discharge portion 6 on the outside rather than the inside of the film blank 2, therefore it would be obvious to one of ordinary skill in the art to modify the article of Ciok so as to provide a layer of material attached to the outside rather than the inside of said film blank 2 (the layer on the inside being film blank 3) to provide an equally effective accommodating means for the discharge portion to that claimed. If there is a design need or a

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market pressure to solve a problem (i.e. providing a discreet housing for the discharge portion) and there are a finite number of identified, predictable solutions (i.e. positions on the film blank for attachment of the comfort layer), a person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation.

Ciok does not teach that at least one opening is provided by a slit in said comfort layer. Austin teaches a single use catheter with a urine container 1 having layer 3 and at least one opening in the form of slit 87 in said comfort layer. Austin teaches that the slit allows access to sleeve 90 for easier attachment and removal of said waste collection container, therefore it would be obvious to one of ordinary skill in the art to modify the device of Ciok so as to have at least one opening in the form of a slit provided in the accommodating means (comfort layer) as taught by Austin so as to provide access to the discharge portion 6 for easier conversion of the portion 6 between its in-use and storage positions. ('834, Figs. 8,9, Col. 3, lines 55-57, Col. 5, lines 35-39)

With respect to **claim 18**: Ciok does not teach that the accommodating element is a comfort layer overlying said one outer film blank 2. However, such a layer attached to the outer film blank is simply another means for housing the discharge portion 6 on the outside rather than the inside of the film blank 2, therefore it would be obvious to one of ordinary skill in the art to modify the article of Ciok so as to provide a layer of material attached to the outside rather than the inside of said film blank 2 (the layer on the inside being film blank 3) to provide an equally effective accommodating means for the discharge portion to that claimed. If there is a design need or a market pressure to solve a problem (i.e. providing a discreet housing for the discharge portion) and there are a finite number of identified, predictable solutions (i.e. positions

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on the film blank for attachment of the comfort layer), a person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation.

Ciok does not teach that at least one opening is provided by a slit in said comfort layer. Austin teaches a single use catheter with a urine container 1 having layer 3 and at least one opening in the form of slit 87 in said comfort layer. Austin teaches that the slit allows access to sleeve 90 for easier attachment and removal of said waste collection container, therefore it would be obvious to one of ordinary skill in the art to modify the device of Ciok so as to have at least one opening in the form of a slit provided in the accommodating means (comfort layer) as taught by Austin so as to provide access to the discharge portion 6 for easier conversion of the portion 6 between its in-use and storage positions. ('834, Figs. 8,9, Col. 3, lines 55-57, Col. 5, lines 35-39)

10. Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ciok ('115) in view of Austin (U.S. Patent No. 4,790,834) as applied to claims 8 and 18 above, and further in view of any one of Kavanagh et al (U.S. Patent No. 6,206,864), Schneider (U.S. Patent No. 5,403,299) and Nolan et al (U.S. Patent No. 4,213,458).

With respect to **claim 9**: Ciok does not teach a reinforcing layer inserted between said one outer film blank 2 and said fairly suggested comfort layer at least in the area of said slit. However, such additional layers to prevent odor from escaping or as faceplates, are well known in the art as supported by Kavanagh, Schneider and Nolan. Therefore it would be obvious to one of ordinary skill in the art to modify the article of Ciok so as to have a reinforcing layer inserted

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between said outer film blank and said fairly suggested comfort layer with a reasonable expectation of success to lend structural integrity to the instant bag member.

With respect to **claim 19**: Ciok does not teach a reinforcing layer inserted between said one outer film blank 2 and said fairly suggested comfort layer at least in the area of said slit.

However, such additional layers to prevent odor from escaping or as faceplates, are well known in the art as supported by Kavanagh, Schneider and Nolan. Therefore it would be obvious to one of ordinary skill in the art to modify the article of Ciok so as to have a reinforcing layer inserted between said outer film blank and said fairly suggested comfort layer with a reasonable expectation of success to lend structural integrity to the instant bag member.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

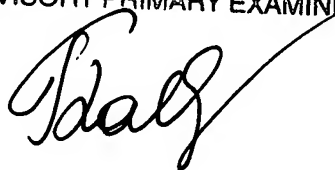
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Melanie J Hand
Examiner
Art Unit 3761

December 15, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', with a long, sweeping horizontal stroke extending to the right.